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MAY 29 2008
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant: Louis WOO
Serial No: 10/685,809
Filed: October 16, 2003
For: DILATORS

Art Unit: 3767
Examiner: Anderson, Michael J.
Attorney Docket: 0119/0017

FEE AUTHORIZATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached herewith is form PTO-2038 authorizing the charge of $510.00 for the filing of the accompanying Appeal Brief for the above-identified Application.

The Commissioner is hereby authorized to debit funds from Deposit Account No. 50-0501 if the amount noted above is insufficient. A duplicate copy of this letter is attached.

Respectfully submitted,

Louis Woo, Reg. No. 31,730
Law Offices of Louis Woo
717 North Fayette Street
Alexandria, VA 22313
Phone: (703) 299-4090

Date: May 29, 2008

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APPEAL BRIEF

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REAL PARTY IN INTEREST

The real party in interest of the subject application is Smiths Group plc to whom the inventor assigned his invention per an Assignment recorded October 16, 2003 on Reel 014614, Frame 0681 at the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

As far as is known, there are no appeals or interferences that are related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-12 are pending in the application, and are being appealed herein.

Being appealed claims 1-12, reproduced in the Claims Appendix, were finally rejected per the Office Action dated January 2, 2008.

STATUS OF AMENDMENTS

There was no amendment filed subsequent to the final rejection Office Action of January 2, 2008.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 1 is directed to a tracheostomy dilator (Figs. 1, 4) that includes a patient end region (3) that is curved, tapered and adapted for insertion through a tracheostomy to expand the tracheostomy as it is being inserted, and a handle region (5) at an end of the dilator opposite to the patient end region. The handle region is curved in an opposite sense from the patient end region. [Page 4, lines 6-10]

Dependent claim 2 defines the dilator to have a passage (10) that extends along the dilator for receiving a guide member. [Fig. 2; page 4, lines 11-12]

Claim 3 depends from claim 2 which in turn depends from claim 1, and recites a tip (2) of the patient end region that provides a substantially stepless transition with an outer surface of the guide member. [Figs. 1, 3; page 5, lines 7-9]

Claim 4 defines the handle region (5) to have a substantially constant diameter along its length. [Figs. 1, 3; page 4, line 4]

Claim 5 defines the handle region (5) to have surface formations (9) to enhance the grip. [Figs. 1-, 3; page 4, line 5]

Claim 6 defines the dilator to be molded from a plastics material. [Page 3, lines 7-8]

Claim 7 defines the plastics material to have a Shore hardness of substantially 90A. [Page 3, lines 7-8]

Claim 8 defines the radius of the curvature of the handle region (5) to be substantially the same as that of the patient end region (3). [Fig. 1; page 4, lines 8-9]

Claim 9 defines the radius of the curvature of the patient end (3) to be about 90mm. [Page 4, line 8]

Claim 10 defines the dilator of claim 1 to include a coating of hydrophillic material along its patient end region. [Page 4, lines 15-16]

Independent claim 11 recites a tracheostomy dilator that has one end providing a handle region (5) and an opposite end providing a flexible, tapered patient end region (3) for insertion to the trachea. The dilator is defined to be smoothly curved along substantially its entire length with an S shape. [Fig. 1, page 3, lines 12-15 and page 4, lines 6-10]

Independent claim 12 recites a tracheostomy dilator that includes a patient end rejection (3) that is tapered along its length [page 3, lines 14-15], an intermediate region (4) that tapers along its length substantially less than the patient end region [page 4, lines 1-3], and a handle end region (5) that has a substantially constant diameter along its length [page 4, lines 4-5]. The dilator has a passage (10) that extends within it and opens at a tip (2) of the patient end rejection to accommodate a guide member along which the dilator is inserted into the trachea [page 2, line 12; page 14, lines 11-12]. The wall thickness of the patient end region is reduced towards the patient end tip so as to provide a smooth transition with an outer surface of the guide member [page 4, lines 12-14; page 5, lines 6-9], and the dilator is curved along substantially its entire length to an S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically [Fig. 4, page 4, lines 6-10; page 5, line 12 to page 6, line 2].

Simply put, the at issue tracheostomy tube dilator is an S shaped dilator that smoothly curves along substantially its entire length, with its handle region curving in an opposite sense as its patient region.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1 and 4-12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ciaglia et al. publication (US 2002/0066453) in view of Toye (US 4,364,391).[1]

Claims 2-3 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ciaglia et al. and Toye and further in view of Fisher (US 4,211,234).

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[1] Even though the rejection in paragraph 3 of the final rejection Office Action of January 2, 2008 did not mention claim 10, claim 10 was referred to and rejected in paragraph 5 of the same Office Action.

ARGUMENT

I. 35 U.S.C. 103(a) rejection of Claims 1 and 4-12 under Ciaglia et al. (US 2002/0066453) in view of Toye (US 4,364,391)

Independent claim 1 specifically recites that the handle region of the claimed tracheostomy dilator is curved in an opposite sense from the patient end region.

Independent claim 11 requires that the dilator be smoothly curved along substantially its entire length with an S shape.

Independent claim 12 requires that the dilator be curved substantially along its entire length to a S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically.

Ciaglia discloses a dilator that is in the shape of a rhinoceros horn, in that there is curvature only from the distal end 20 to the demarcation line 22 (and possibly to insertion line 26) at the tapered distal portion 16 of the dilator. See Fig. 2. Indeed, Ciaglia discloses throughout that it is only the tapered distal portion 16 that is curved. See for example the first sentence in paragraph 0016 and first sentence in paragraph 0018. Ciaglia states in particular the following in the first sentence of paragraph 0019: "The curvature of curved tapered distal portion 16 may be a series of curves of different radii, or a complex curve, from distal end 20 at least to demarcation 22."

Even though conceding that Ciaglia fails to disclose a handle region of a dilator curved in an opposite sense as the patient end region, the examiner nonetheless asserts that Toye does disclose a curved handle region, identifying element 24 in Fig. 11 of Toye as such.[2] The examiner amplifies this rejection in his response to arguments, namely in the sentence bridging pages 4 and 5 of the Office Action, by stating: "Toye ('391) discloses a dilator with a handle (24) and tube (60) portion curved opposite the curved introducer (figure11) and further discloses gripping features as stated."

---

[2] See paragraph 4 bridging pages 2 and 3 of the final rejection Office Action dated January 2, 2008.

Toye discloses a dilator 30 that has a handle portion 32 that extends to a curved intermediate portion 34 and a conical introducer portion 36. As shown in Fig. 4, a complementally curved metal tracheal tube 42 is coaxially fitted over the curved intermediate portion 34 of the dilator (column 4, lines 38-60). The insertion of trachea tube 42 into the patient and the withdrawal of dilator 30 from the trachea tube is shown in Figs. 7-10. Fig. 11, which is relied by the examiner for his rejections, is disclosed by Toye as being utilized in a situation where the patient cannot breathe normally through the tracheal tube, and thus requires the assistance of a respirator. Hence the different trachea tube 54 shown in Fig. 11 (column 5, lines 63-68). The trachea tube of Fig. 11, in order to work with a respirator, has to be air tight with the trachea wall of the patient. Accordingly, trachea tube 54 has an inflatable cuff 58 which, in order to be inflated within the trachea of the patient, is connected by means of an air tubing 60 to a bladder 62, which in turn is connected to a syringe 24. It is by depressing the plunger 28 to force air from syringe 24 through air tubing 60 into cuff 58 that cuff 58 is inflated (column 6, lines 28-43, lines 53-54).

Thus, the first element relied upon by the examiner, namely the syringe 24, is not a part of the dilator. And even assuming that it were, note that the syringe is a straight barrel device and does not curve in any sense. As for the air tube 60, it should be appreciated that air tubing 60 is but a thin lumen that is connected to cuff 58 of the tracheostomy tube 54, and is in fact flexible in all regards. In other words, air tubing 60 is not and could not be the handle of the tracheostomy tube. And the happenstance that it has been drawn in a curved orientation does not make it the handle of the tracheostomy tube.

In fact, Fig. 11 does not show a tracheostomy dilator, for as discussed above, the tracheostomy tube 56 is not a dilator -- for in order to be inserted into the trachea of a patient, tracheostomy tube 56 has to be first fitted with a dilator, which is removed upon insertion of the tracheostomy tube into the trachea of the patient.

Accordingly, appellant respectfully submits that (1) Toye fails to disclose a curved handle for a tracheostomy dilator, and (2) the reliance by the examiner on Fig. 11 is totally misplaced, inasmuch as Fig. 11 shows a tracheostomy tube connected by its air tubing to a syringe, not a tracheostomy dilator that is used to place a tracheostomy tube into the patient or to prepare the opening into the trachea for insertion of the tracheostomy tube.

In *Alza Corp. v. Mylan Lab*, 464 F.3d 1286, 1290-1291 (2006)[3] the CAFC states: "To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, the Board must provide some rationale, articulation or reasoned basis to explain why the conclusion of obviousness is correct. ... However, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See also *KSR Int'l v Teleflex Inc.,* at pp 14-15 of slip opinion issued April 30, 2007.

In the light of guidance provided by the courts, appellant respectfully submits that the examiner has not provided any rational underpinning to support his obviousness rejection, for there is nothing in Toye that remotely suggests that the handle portion of a tracheostomy dilator is curved, let alone curved in the opposite sense from the patient end region as required in claim 1, or that the dilator be in the shape of an S, as required in claims 11 and 12.

In view of the above, appellant respectfully submits that the rejection of independent claims 1, 11 and 12, and claims 4-10 dependent from claim 1, is without merit and not sustainable.

II. The 35 U.S.C. §103(a) rejection of claims 2-3 under the combination of Ciaglia, Toye and Fisher (US 4,211,234)

Fisher discloses an endotracheal tube introducer 22 that has a mouthpiece 26, a longitudinal slot 25, an upper flange 27, and an elongate member 28 that has three guide ribs 30, 32 and 34. The Fisher introducer is therefore not even similar to the tracheostomy dilator disclosed in Ciaglia and Toye. Be that as it may, the fact that claims 2 and 3 respectively depend directly and indirectly from claim 1 render those claims not obvious over the combination of Ciaglia, Toye and Fisher, in light of the discussion above with respect to independent claim 1.

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[3] The *Alza* case was cited by the Supreme Court in *KSR Int'l Cov Teleflex Inc.*, 550 US ___, 127 S Ct. 1727, 167 L. Ed. 2d 705 (2007), in which the Court noted approvingly the *Alza* court's obviousness analysis of the claimed invention, at pages 17-18 of slip opinion issued April 30, 2007.

Conclusion

For the reasons pointed out above, appellant respectfully submits that the pending claims on appeal are patentably distinguishable over the cited references and that the examiner's rejections accordingly are without merit and not sustainable. The Board is therefore respectfully requested to reverse the examiner's rejections.

Respectfully submitted,

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Date: May 29, 2008

CLAIMS APPENDIX

1. A tracheostomy dilator comprising: a patient end region, said patient end region being curved, tapered and adapted for insertion through a tracheostomy to expand the tracheostomy as it is inserted; and a handle region at an end of the dilator opposite said patient end region, wherein said handle region is curved in an opposite sense from said patient end region.

2. A dilator according to Claim 1, wherein said dilator has a passage extending along it for receiving a guide member.

3. A dilator according to Claim 2, wherein a tip of said patient end region provides a substantially stepless transition with an outer surface of said guide member.

4. A dilator according to Claim 1, wherein said handle region has a substantially constant diameter along its length.

5. A dilator according to Claim 1, wherein said handle region has surface formations adapted to enhance grip.

6. A dilator according to Claim 1, wherein said dilator is moulded of a plastics material.

7. A dilator according to Claim 6, wherein said plastics material has a Shore hardness of substantially 90A.

8. A dilator according to Claim 1, wherein the radius of a curvature of said handle region is substantially the same as that of said patient end region.

9. A dilator according to Claim 1, wherein the radius of curvature of said patient end is about 90mm.

10. A dilator according to Claim 1 including a coating of a hydrophilic material along its patient end region.

11. A tracheostomy dilator comprising one end providing a handle region and an opposite end providing a flexible, tapered patient end region for insertion to the trachea, wherein said dilator is smoothly curved along substantially its entire length with an S shape.

12. A tracheostomy dilator comprising: a patient end region, said patient end region tapering along its length; an intermediate region, said intermediate region tapering along its length substantially less than said patient end region; and a handle end region, said handle end region having a substantially constant diameter along its length, wherein said dilator has a passage extending within it and opening at a tip of said patient end region to accommodate a guide member along which said dilator is inserted to the trachea, wherein the wall thickness of said patient end region reduces towards a patient end tip such as to form a smooth transition with an outer surface of said guide member, and wherein said dilator is curved along substantially its entire length to an S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.